Medtronic
XOMED

NIM-Response® 2.0
Patient Simulator

USER'S GUIDE

NIM Help line
1-800-874-5797
For Questions and Service

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LIMITED WARRANTY

A. This LIMITED WARRANTY provides assurance for the customer who purchases a NIM-Response® 2.0 Patient Simulator (hereinafter the "Product") that should the Product fail to function to Medtronic Xomed's published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment), Medtronic Xomed will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Medtronic Xomed or from its affiliate or its authorized distributor or representative.

B. To qualify for this LIMITED WARRANTY, the following conditions must be met:
   (1) The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
   (2) The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
   (3) Medtronic Xomed must be notified in writing within thirty (30) days following discovery of a defect.
   (4) The Product must be returned to Medtronic Xomed within thirty (30) days of Medtronic Xomed receiving notice as provided for in (3) above.
   (5) Upon examination of the Product by Medtronic Xomed, Medtronic Xomed shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Xomed or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.

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CAUTION

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RETURNS AND/OR REPAIRS

Medtronic Xomed Customer Service
800-872-9877
904-296-6448 (FAX)
Monday – Friday
8:00 AM – 5:00 PM E.S.T.
www.xomed.com

Note: When contacting our Customer Service and Technical Support, please have:
- Product Number
- Product Serial Number
- Date of Purchase
- Nature of Inquiry Available.

⚠ **PRECAUTIONS**

To avoid cross contamination and ensure aseptic technique, use of the Patient Simulator is not recommended for use in a clinical setting.

CUSTOMER SERVICE

U.S. CUSTOMER SERVICE
General customer service and technical support are available toll-free:
800-874-5797 or 904-296-9600
Monday-Friday 8:00 AM – 6:00 PM E.S.T.
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MICROELECTRONICS REPAIR
Technical Support:
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Return Address:
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6743 Southpoint Drive North
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Attn.: Repair Department

INTERNATIONAL SERVICE
International customers should contact their local Medtronic Xomed office:

AUSTRALIA:	61-2-9879-5999
CANADA:	905-826-6020
FRANCE :	33-4-7067-9800
U.K.:	44-1454-619555
GERMANY:	49-89-32140060
THE NETHERLANDS:	31-40-2333888
BELGIUM:	32-2-4560900

or their local distributor.

THE NIM-Response® 2.0 HELPLINE
Should you need immediate help with a technical question or guidance through the appropriate protocol, just call the NIM-Response® 2.0 Help Line at 1-800-874-5797.

NOTE:
When contacting our Customer Service and Technical Support, please have the appropriate product number, product serial number, date of purchase, and nature of inquiry available.

Product Number

Serial Number

Date of Purchase

SYMBOLS

⚠	Attention, See Instructions For Use
REF	Catalog Number
SN	Serial Number
	Date Of Manufacture
LOT	Lot Number
CE 0123	CE Mark

The Medtronic Xomed NIM-Response® 2.0 Patient Simulator provides for test of the NIM-Response® 2.0 system without the usual need for patient interaction. The NIM-Response® 2.0 Patient Simulator facilitates test of some of the features that the NIM-Response® 2.0 offers for patient care. In addition, the NIM-Response® 2.0 Patient Simulator is a convenient means of testing various aspects of instrument operability prior to patient application.
The NIM-Response® 2.0 Simulator is capable of demonstrating the following features:

- Recording electrode off condition
- Electrode impedances and difference condition
- Stimulus Presentation
  - Stimulus: Set and Measure
  - Event Threshold

This manual should be used in conjunction with the NIM-Response® 2.0 User's Guide. Refer to the User's Guide for complete NIM-Response® 2.0 operating instructions.

INTENDED USE

The Patient Simulator is intended for use in troubleshooting and demonstrating the operation of the NIM-Response® 2.0. It is primarily intended to serve as a "patient" for the NIM-Response® 2.0, and can be used to demonstrate the normal operation of the NIM-Response® 2.0 as well as demonstrating a lead-off condition, stimulation and mechanical response.

INDICATIONS

The Patient Simulator is intended for use as a training and troubleshooting aid in a non-clinical setting.

CONTRAINDICATIONS

None are known.

This section describes the NIM-Response® 2.0 Patient Simulator and pertinent components of the NIM-Response® 2.0 system used during a test. These include the NIM-Response® 2.0 Patient Simulator device, the NIM-Response® 2.0 Patient Interface and the Touch Screen.

NIM-Response® 2.0 PATIENT SIMULATOR

Colored wires and connectors protrude from the end of the simulator. These cables connect to the corresponding jacks on the NIM-Response® 2.0 Patient Interface.

On the NIM-Response® 2.0 Patient Simulator, there is one stimulation contact each, for Ch 1 through Ch 4. These contacts are the points for activating individual circuits. A monopolar stimulator probe instrument (connected to STIM1 - (negative)) is recommended for use during testing to stimulate the channel circuits.

NIM-Response® 2.0 PATIENT INTERFACE CONNECTION

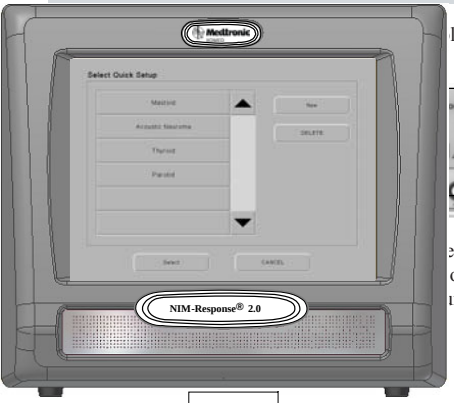

Fig 6

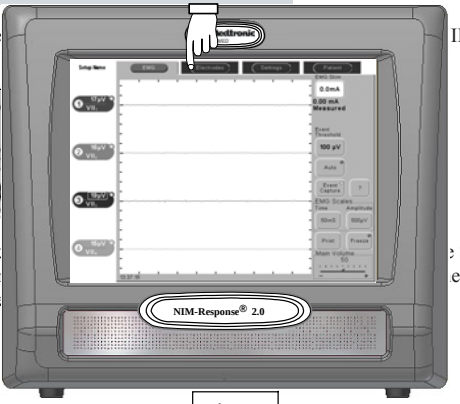

Fig 7

SIMULATOR SETUP

Simulator use requires prior setup of the NIM-Response® 2.0 unit as described in the NIM-Response® 2.0 User's Guide. Be sure to follow all pertinent cautions, warnings, and operating instructions found in each section of the User's Guide.

Follow these steps to set up the system for Simulator use:

1. Connect all channel jumper cables from the simulator to the corresponding Patient Interface (Colored connectors with colored wire to POSITIVE jacks, colored connectors with black wires to NEGATIVE jacks).
2. Connect the red connector with white wire to the Stim 1 positive (+) jack on the Patient Interface.
3. Connect the green connector with green wire to the ground jack on the Patient Interface.
4. Connect a Monopolar stimulator to the Stim 1 negative (black) jack on the Patient Interface.

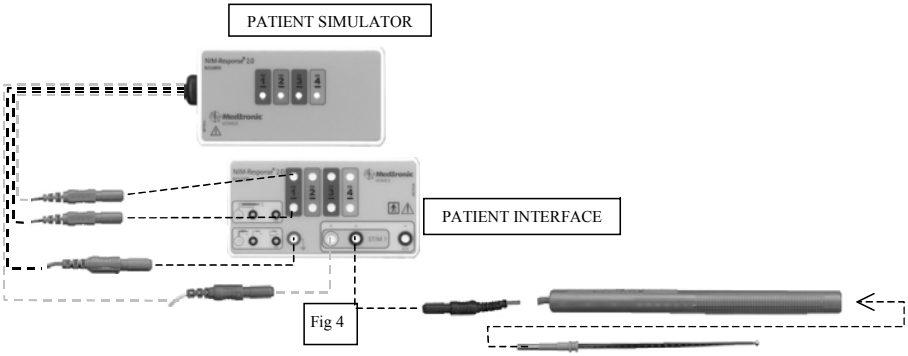

Fig 4

Wiring Reference			
Connector Color	**Wire Color**	**Channel #**	**Connects To**
Blue	Blue	1	Patient Interface Positive
Blue	Black	1	Patient Interface Negative
Red	Red	2	Patient Interface Positive
Red	Black	2	Patient Interface Negative
Purple	Purple	3	Patient Interface Positive
Purple	Black	3	Patient Interface Negative
Orange	Orange	4	Patient Interface Positive
Orange	Black	4	Patient Interface Negative
Red	White	N/A	Patient Interface Stim 1 +
Green	Green	N/A	Patient Interface Ground

CONNECTING TO THE NIM-Response® 2.0 (FRONT AND REAR PANEL)

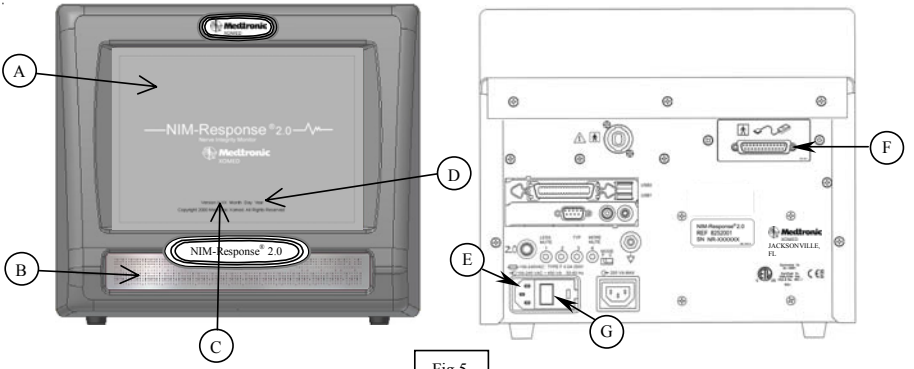

Fig 5

A. TOUCH SCREEN displays EMG waveforms and controls many functions of the monitor.
B. SPEAKER provides audio alarms, acoustic EMG monitoring, and voice prompts.
C. SOFTWARE Version installed.
D. CURRENT date.
E. POWER CONNECTOR
F. PATIENT INTERFACE CONNECTOR
G. ON/OFF POWER SWITCH

1. Connect the "Patient Interface" to connector "F" on the back of the NIM-Response® 2.0.
2. Connect the "AC Power Cord" to connector "E".

CONFIRMING ELECTRODES

This check confirms that all electrode circuits are connected and functioning properly.

1. Turn on the “Power Switch”.
   - The NIM-Response® 2.0 will perform a series of self test during the “Boot Up” process **DO NOT TOUCH THE SCREEN AT THIS TIME.**
     - This process takes about 40 seconds.
2. The first touch screen to open will be the “Select Quick Setup” screen (see fig 6).
   - **DO NOT TOUCH THE SCREEN AT THIS TIME.**
   - This default screen will turn off after about 40 seconds.

3. The next screen to open will be the “EMG Monitoring” screen (see fig 7).
4. ***Press***

   - The monitoring screen will close and the electrodes screen will open.

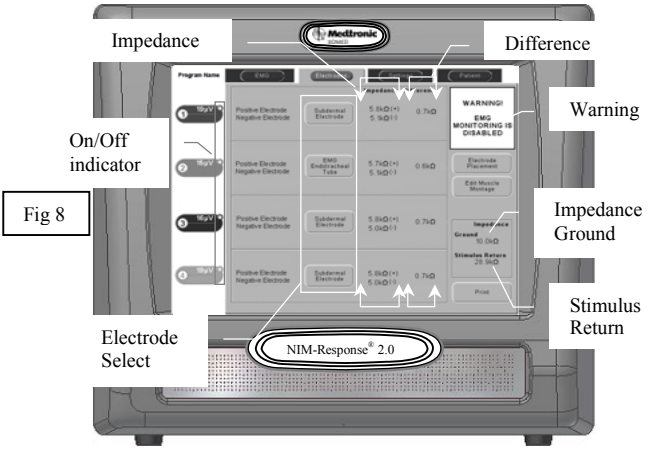

Fig 8

3. Electrodes screen opens (fig 8). - At this display confirm:
   - All channels are ON.
     - There are ON/OFF indicators in the upper right of each channel button. ON = GREEN.
   - All channels have "Subdermal Electrode" selected.
   - Positive and negative impedance of all 4 channels is 5.0 kΩ ± 0.3 kΩ or 5.6 kΩ ± 0.3 kΩ.
   - The difference in their values is 0.5 kΩ ± 0.3 kΩ.
   - The impedance of the Ground is 10.0 kΩ ± 0.6 kΩ.
   - The impedance of the Stimulus Return is 29.0 kΩ ± 4.0 kΩ.
   - Warning "Monitoring is Disabled" is on and flashing.

ELECTRODE LEAD OFF

This test simulates what happens when contact with an electrode is lost. (See fig 9)

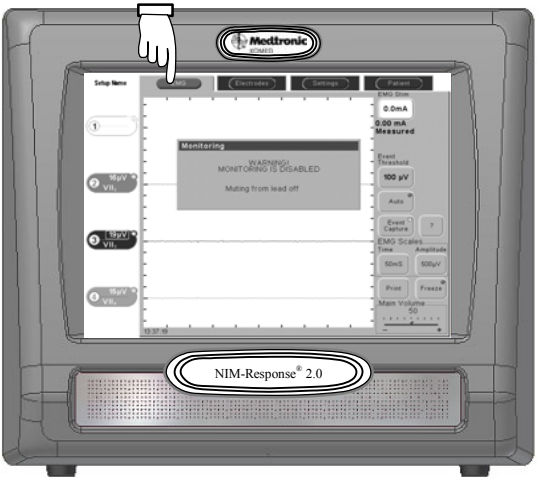

Fig 9

1. ***Press***

   .
   - Electrodes screen will close and EMG Monitoring screen will open.
2. Disconnect either lead from Channel 1(fig 9).
   - The touch screen displays a flashing Channel 1.
   - The touch screen displays a Warning in the center of the screen.
   - After 20 to 30 seconds, the NIM-Response® 2.0 sounds the "Bleedle" alarm (a three-note alarm "BLEE-dle DEET") and enunciates "Check Electrodes".

3. The Electrodes Screen opens (fig 10).

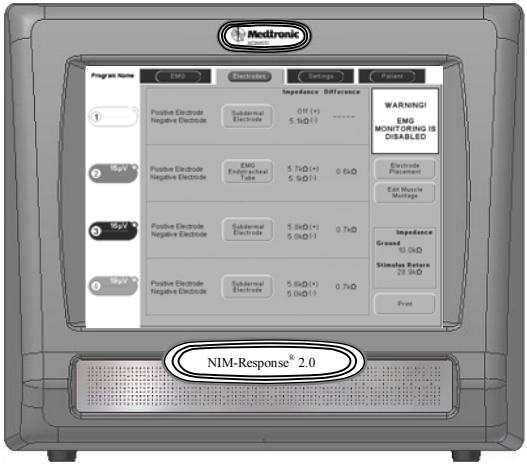

Fig 10

- The touch screen (fig 10) displays a flashing Channel 1.
- The touch screen displays a flashing Warning.
- Channel 1 will display "Off" for "Impedance" and "- - - - -" for "Difference".
- The Bleedle Alarm sounds every twenty (20) seconds.

4. Reconnect the Channel 1 lead.
   - Confirm: the NIM-Response® 2.0 returns to normal operation.
5. Repeat the test for Channels 2 through 4.

MECHANICAL STIMULATION

The positive and negative jumper cables for Channels 1 through 4 are sensitive to touch (Mechanical Stimulation) and will generate EMG and coded tone responses when manipulated. These simulated responses appear as spontaneous burst-like responses in both the audio and visual signals.

1. ***Press***

.
2. EMG Monitoring Screen will open.
3. Lightly tap the jumper cables.
   - Observe:
     - You should hear single beep alarms at each channel tapped.
     - Alarm tones change at each channel.
     - You should see sharp (spike like) waveforms on the screen.
     - Tapping multiple cables will produce multiple alarms and waveforms. (see fig 11)

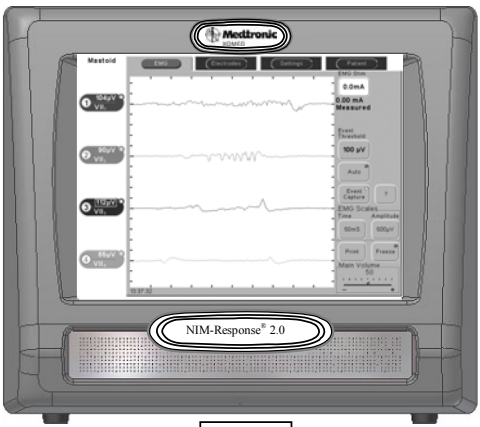

Fig 11

EMG STIMULATING AND TONES

1. Increase EMG Stim to 1.0 mA (see fig 12).
   a. In the upper right of the screen, press the EMG Stim (0.0 mA) button.
   b. This will open a dropdown menu consisting of five buttons, four arrow and one zero.
   c. Press the SMALL up arrow until 1.0 mA is displayed on the EMG Stim button.
   d. Buttons will turn off after a few seconds.
2. Touch and hold the stimulating probe to channel 1 of the Patient Simulator.
   - Observe: (see fig 13)
     - Waveform on channel 1.
     - Stimulus tone sounds (repeating beep).
     - Raw EMG can be heard (a popping sound accompanying the stimulus tone).
     - mA Measured is 1.0 mA ± 0.02 mA or 5% of applied mA.
3. While maintaining contact with the simulator, increase the Event Threshold (see fig 14, use large up arrow) until the stimulus pulse no longer triggers a tone.
   - Note that the raw EMG can still be heard (a popping sound).
4. Remove probe. Note that waveform remained on screen (if not check Event Thresholds button's on/off indicator is green).
5. Repeat for remaining channels.

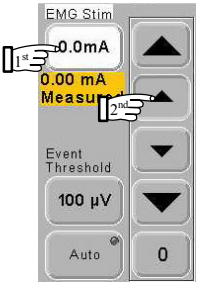

Fig 12

Fig 13

BAS

1. I
   (
   a
   b
   c he
   d. Buttons will turn off after a few seconds.
   At this point, the monitor will be picking up large amounts of electronic noise causing multiple event tones to sound. It is also helpful to hold the channel 1 electrode between two fingers.

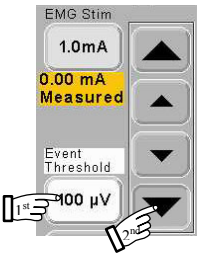

Fig 14

2. ***Press*** Auto (on/off indicator turns green).
   - Observe continuous event alarms sounding for 20-30 seconds.
   - After 20-30 seconds, Baseline Increase is announced.
   - Baseline activity is displayed on the screen.

NOTE: Vary the Audio and other settings used in this test to become more familiar with the NIM.

CLEANING

- The Patient Simulator enclosure is not waterproof. **DO NOT** immerse the Patient Simulator.
- **DO NOT** attempt to sterilize the Patient Simulator.
- Dampen a soft cloth with disinfectant or mild detergent and water.
  - NOTE: Cloth must not be dripping wet.
- Thoroughly wipe the Patient Simulator and cables, removing all visible debris.
- Allow the Patient Simulator to thoroughly air dry before storing.

TROUBLESHOOTING

Should you encounter any difficulty eliciting simulated responses from the NIM-Response® 2.0 PATIENT SIMULATOR, check the following:

- Verify that Stimulus Measured is approximately the same as Stimulus Intensity.
- Make sure the jumper cables are connected correspondingly between the SIMULATOR and PATIENT INTERFACE.
- Adjust the EVENT THRESHOLD setting on the NIM-Response® 2.0.
- Adjust the STIMULUS intensity on the NIM-Response® 2.0 for adequate output.
- Clean the stimulator contacts of debris.
- Check the integrity of the stimulator or stimulus-dissection instrument and its connecting cable.
- Check for blown fuse in NIM-Response® 2.0 Patient Interface and replace with proper valued fuse (shown near fuse box).
- Check for proper closure of fuse holder in the NIM-Response® 2.0 Patient Interface.

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